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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 226536	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/US04/08960	International filing date *(day/month/year)* 24 March 2004 (24.03.2004)	Priority date *(day/month/year)* 24 March 2003 (24.03.2003)
International Patent Classification (IPC) or national classification and IPC IPC(7): C12N 5/10; G01N 33/53, 33/566 and US Cl.: 435/325, 372, 7.24, 7.1		
Applicant THE GOVERNMENT OF THE UNITED STATES, AS REPRESENTED BY THE SECRETARY, DEPARTMENT OF HEALTH AHD HUMAN SERVICES		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *(sent to the applicant and to the International Bureau)* a total of ___ sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
08 October 2004 (08.10.2004)	20 March 2005 (20.03.2005)
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Ron Schwadron, Ph.D. Telephone No. 571 272 1600

Form PCT/IPEA/409 (cover sheet)(January 2004)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/08960

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3 and 23.1(b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☒ the description:
pages 1-30 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

☒ the claims:
pages 31-38 as originally filed/furnished
pages* NONE as amended (together with any statement) under Article 19
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

☐ the drawings:
pages NONE as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/figs _____
☐ the sequence listing (*specify*): _____
☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/figs _____
☐ the sequence listing (*specify*): _____
☐ any table(s) related to the sequence listing (*specify*): _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 9,13-16,25-36,41 and 50

because:

☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 9,13-16,25-36,41 and 50 are so unclear that no meaningful opinion could be formed *(specify)*:

The aforementioned claims will not be examine because they are improper multiple dependent claims (9,13-16,25-28,41,50) or indefinite (29-36). Claims 29-36 are indefinite because claim 29 refers to the "method of claim 1", but claim 1 is not drawn to a method.

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form
- ☐ has not been furnished
- ☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-5,22,37-40,42-49	YES
	Claims 6-8,10-12,17-21,23,24	NO
Inventive Step (IS)	Claims NONE	YES
	Claims 1-8,10-12,17-24,37-40,42-49	NO
Industrial Applicability (IA)	Claims 1-8,10-12,17-24,37-40,42-49	YES
	Claims NONE	NO

2. Citations and Explanations (Rule 70.7)
Claims 6-8,10-12,17-21,23,24 lack novelty under PCT Article 33(2) as being anticipated by US 2002/0049302.

US 2002/0049302 discloses APC transfected with fluorescence peptide labeled MHC fusion molecule and use of said cells in an assay to detect/quantify and purify T cells specific for a peptide, wherein the T cells internalize labeled MHC/peptide complexes presented on the surface of the APC (see [0002]-[0008], [0013]. The internalization of said complex signals a T cell mediated immune response. US 2002/0049302 discloses that the internalized MHC fusion protein/peptide complex is detected using the FACs (see [00013]). US 2002/0049302 discloses use of human PBMCs in said method (see [0010]. The peptide is introduced into the cell in peptide form or by transfection
(see [0010]-[0011]). The QL9 peptide used is 9 amino acids(see [0010]).

Claims 1-8,10-12,17-24,37-40,42-49 lack an inventive step under PCT Article 33(3) as being obvious over US 2002/0049302 in view of US 6,461,867.

US 2002/0049302 discloses APC transfected with green fluorescence peptide labeled MHC fusion molecule and use of said cells in an assay to detect/quantify and purify T cells specific for a peptide, wherein the T cells internalize labeled MHC/peptide complexes presented on the surface of the APC (see [0002]-[0008], [0013]. The internalization of said complex signals a T cell mediated immune response. US 2002/0049302 discloses that the internalized MHC fusion protein/peptide complex is detected using the FACs (see [00013]). US 2002/0049302 discloses use of human PBMCs in said method (see [0010]. The peptide is introduced into the cell in peptide form or by transfection
(see [0010]-[0011]). The QL9 peptide used is 9 amino acids(see [0010]).
US 6,461,867 discloses APC transfected with more than one MHC molecule (see claim 1). A routineer would have transfected the cells of US 2002/0049302 with more than 1 labeled MHC/fusion protein for use in humans wherein the art recognizes that humans are heterozygous at the MHC locus. HLA 201 is the most commonly found MHC class I allele in humans. Mutliparameter FACs analysis using different fluorescent molecules is well known in the art. The method could have been used to characterize any T cell subset response identified using an art recognized marker. The aforementioned methods could have been used to screen for potential peptides used for vaccines .

---------- NEW CITATIONS ----------